4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0021]

Actavis Totowa LLC, et al.; Withdrawal of Approval of Abbreviated New Drug Applications for Prescription Pain Medications Containing More Than 325 Milligrams of Acetaminophen; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the Federal Register of March 27, 2014 (79 FR 17163). The document withdrew approval of 108 abbreviated new drug applications (ANDAs) for prescription pain medications containing more than 325 milligrams (mg) of acetaminophen per dosage unit from multiple applicants, effective March 27, 2014. The document failed to withdraw approval of ANDAs 040825, 040822, and 040824, held by Ranbaxy Laboratories Inc. and Ranbaxy Inc., 600 College Rd. East, Princeton, NJ 08540, and ANDA 040182, held by Pharmaceutical Associates, Inc., 201 Delaware St., Greenville, SC 29605. The holders of these applications have voluntarily requested that approval of these applications be withdrawn and have waived their opportunity for a hearing. FDA confirms the withdrawal of approval of ANDAs 040825, 040824, 040822, and 040182.

FOR FURTHER INFORMATION CONTACT: Rachel Turow, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6236, Silver Spring, MD 20993-0002, 301-796-5094.

SUPPLEMENTARY INFORMATION: In FR Doc. 2014-06801, appearing on page 17163, in the Federal Register of Thursday, March 27, 2014, the following correction is made:

On page 17166, in table 1, the following entries are added in alphabetical order by Applicant:

Application No.	Drug Product(s)	Applicant or Holder
ANDA 040182	Acetaminophen and Hydrocodone Bitartrate Oral Solution, 7.5 mg/500 mg/15 milliters (mL), available in 473 mL, 118 mL, 15 mL, and 10 mL	Pharmaceutical Associates, Inc., 201 Delaware St., Greenville, SC 29605
ANDA 040825	Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/5 mg	Ranbaxy Laboratories Inc., 600 College Rd. East, Princeton, NJ 08540
ANDA 040822	Acetaminophen and Hydrocodone Bitartrate Tablets, 750 mg/7.5 mg	Do.
ANDA 040824	Acetaminophen and Hydrocodone Bitartrate Tablets, 500 mg/10 mg	Ranbaxy Inc., 600 College Rd. East, Princeton, NJ 08540

Dated: April 24, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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